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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,853	12/14/2004	Satoshi Yonehara	10873.1578USWO	9018

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EXAMINER	
MARTIN, PAUL C	
ART UNIT	**PAPER NUMBER**
1657	

MAIL DATE	DELIVERY MODE
07/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,853	YONEHARA ET AL.	
	Examiner	Art Unit	
	Paul C. Martin	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6-19 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 6-19 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3, 6-19 and 21 are pending in this application and were examined on their merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/05/07 has been entered.

The rejection of Claims 1, 3 and 6-21 under 35 U.S.C. § 112, 2nd paragraph as being indefinite has been withdrawn due to the Applicant's amendments to the Claims filed 06/05/07.

Claim Rejections - 35 USC § 103

Claims 1, 3, 6-19 and 21 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Komori *et al.* (US 2002/0025546 A1) in view of Oshiro *et al.* (1982) for reasons of record set forth both in the Advisory Action mailed 5/24/07 and the Final Action mailed 01/05/07.

Claims 1, 3, 6-19 and 21 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Komori *et al.* (US 2002/0025546 A1) in view of Merabet *et al.* (US 2002/0173043 A1).

Komori *et al.* teaches a method for measuring an analyte in a sample containing hemoglobin by using a redox reaction, and adding a nitro compound (2-(4-iodophenyl)-3-(2,4-dinitrophenol-5-(2,4,-disulfophenyl-2H-tetrasolium salt, hereafter referred to as WST-3) to the sample so as to eliminate the influence of hemoglobin contained in the sample, forming an a reducing substance or an oxidizing substance derived from the analyte, and determining the amount of the from the quantity of the formed substance. (Column 1, Lines 4-18).

Komori *et al.* teaches adding both the nitro compound WST-3 and a surfactant such as Triton X-100 to the sample. (Page 4, Column 1, Lines 2-17)

Komori *et al.* teaches that the redox reaction is a color development reaction caused by reducing the oxidizing substance derived from the analyte (hydrogen peroxide) and oxidizing a substrate that develops color by oxidation using an oxidase (peroxidase), wherein the amount of oxidizing substance developed is quantified by the degree of color development. (Page 12, Column 2, Claims 13 and 14).

Komori *et al.* teaches that the degree of color development is measured by measuring at a wavelength for detecting the substrate. (Page 5, Column 1, Lines 4-11).

Komori *et al.* teaches that the analyte can be glycated protein, glycated peptides, or glycated amino acids and hydrogen peroxide is formed as the oxidizing substance derived from the analyte by causing a fructosyl amino acid oxidase (FAOD) to act on the analyte, (Page 3, Column 1, Lines 12-19) and the addition of a surfactant and a nitro compound to the sample before causing the FAOD to act on the analyte. (Page 4, Column 1 Lines 5-16 and Column 2, Lines 18-21)

Komori *et al.* teaches the use of the above steps with a color developing substrate N-(carboxymethylaminocarbonyl)-4,4'-bis(dimethylamino)diphenylamine sodium salt, a combination of Trinder's reagent and 4-aminoantipyrine (Page 4, Column 2, Lines 39-43)

Komori *et al.* teaches the glycated protein can be glycated hemoglobin and the hemolyzed sample is obtained by hemolyzing erythrocytes (Page 3, Column 1, Lines 3-11)

Komori *et al.* teaches the addition of a surfactant to a sample, the surfactant concentration between 0.01 to 5% by weight, (Page 4, Column 1, Lines 13-15) and the addition of the nitro compound to a sample so that its concentration is between 0.4 to 200mmol/L when the concentration of blood cells in the sample is from 1-10% by volume. (Page 4, Column 1, Lines 19-30)

Komori *et al.* does not teach the use of a sulfur-containing compound or any of the claimed nitrogen-containing compounds.

Komori *et al.* does not teach the use of N,N,N',N',N",N",-hexa(3-sulfopropyl)-4,4',4"-triaminotriphenylmethane hexasodium salt, or N,N,N',N',N",N",-hexa(2-hydroxy-3-sulfopropyl)-4,4',4"-triaminotriphenylmethane hexasodium salt, or 10-(carboxymethylaminocarbonyl)3,7-bis(dimethylamino)phenothiazine sodium salt, or 10-(methylaminocarbony)3,7-bis(dimthylamino) phenothizine sodium salt.

Komori *et al.* does not teach the addition of a sulfur-containing compound to a sample so that its concentration is between 0.05-200mmol/L when a concentration of blood cells in the sample is 1% by volume.

Komori *et al.* does not teach the addition of the nitro compound to a sample so that its concentration is between 0.05-500mmol/L when a concentration of blood cells is 1% by volume.

Komori *et al.* does not teach the addition of a sulfur-containing compound and a nitrogen-containing compound to a sample so that their respective concentrations are 0.05 to 200mmmol/L and 0.05 to 250mmol/L when a concentration of blood cells in the sample is 1% by volume.

Merabet *et al.* teaches a composition and method for detecting hemoglobin in a sample, comprising sodium lauryl sulfate or Triton-X-100 as a erythrolytic agent, and sodium nitrite to completely oxidize hemoglobin to methemoglobin and bind it stably (Pg. 2, Paragraphs [0027]-[0028] and [0031]-[0032]), and that the advantage of the assay over the prior art is the ability to be used with other assays at pH close to physiological (pH 9) (Pg. 1, Paragraph [0008]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the redox method for measuring an analyte in a sample containing hemoglobin as taught by Komori *et al.* with the use of the composition comprising the sulfur-containing compound sodium lauryl sufate (SLS) and the nitrogen-containing compound sodium nitrite because as it was known in the art at the time of the instant invention that aromatic nitro compounds oxidize hemoglobin and neutralize its interfering characteristics in redox reactions, it would have been obvious to the ordinary artisan to include a nitro compound in the pre-treatment step prior to the redox reaction to neutralize the effects of any free hemoglobin which could otherwise have interfered with the impending redox reaction. One of skill in the art would have recognized that the nitro compounds and surfactants of Komori *et al.* were functionally equivalent to the nitro compounds and surfactants taught by Merabet *et al.* and would have functioned in an equivalent manner in eliminating the influence of hemoglobin. One of ordinary skill in the art would have been motivated to make this modification because of the advantages taught by Merabet *et al.* such as the ability to combine the oxidation and binding of hemoglobin with other assays at physiological pH.

Although Komori *et al.* did not teach the color developing substrates of Claim 13, it is deemed that the 10-(carboxymethylaminocarbonyl)3,7-bis(dimethylamino) phenothiazine sodium salt and 10-(carboxymethyl-4-benzaminocarbonyl)3,7-bis(dimethylamino) phenothiazine sodium salt are obvious variants of N-(carboxymethylaminocarbonyl)-4,4'-bis(dimethylamino) diphenylamine sodium salt found in Claim 12. The ordinary artisan would have had a reasonable expectation that the 10-(carboxymethyl...) compounds would have acted as functional equivalent color developing substrates to N-(carboxymethylaminocarbonyl)-4,4'-bis(dimethylamino) diphenylamine sodium salt.

With regard to the concentrations not taught by Komori *et al.* the MPEP states:

"Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.")"

One of ordinary skill in the art at the time of the instant invention would have been motivated to experiment with the addition of the nitrogen-containing compound and the sulfur-containing compound singularly, and in conjunction, in order to test for negative results caused by an individual component before the attempting of the experiment using the two compounds simultaneously. The ordinary artisan would also have been motivated to adjust the concentrations of the compounds in order to optimize the experiment and achieve the best possible results. There would have been a reasonable expectation of success in combining these two references because both are drawn to the use of nitrogen compounds and similar surfactants in the assays involving hemoglobin.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed 06/05/07 have been fully considered but they are not persuasive.

The Applicant argues that there is no suggestion or motivation to combine Komori *et al.* with Oshiro *et al.* which require adding an oxidative enzyme in the step of forming an oxidizing substance derived from the analyte to be measured, and that US 2003/0186449 teaches away from the use of SLS for use with enzymes as the reagent adversely affects the enzyme system and that the two references are directed to different subject matter (denaturation of hemoglobin by SLS and alkali in the case of Oshiro *et al.* and enzymatic determination of an analyte in a sample containing hemoglobin in the case of Komori *et al.*).

This is not found to be persuasive for the following reasons, Komori *et al.* clearly teaches adding an oxidative enzyme in the step of forming an oxidizing substance derived from the analyte to be measured, "...the redox reaction is a color development reaction caused by reducing the oxidizing substance derived from the analyte (hydrogen peroxide) and oxidizing a substrate that develops color by oxidation using an oxidase (peroxidase), wherein the amount of oxidizing substance developed is quantified by the degree of color development." (Page 12, Column 2, Claims 13 and 14), and the cited reference US 2003/0186449 is directed, as was the Oshiro *et al.* reference to the use of SLS in conjunction with an alkali substance. Komori *et al.* taught the use of nitrogen containing compounds with surfactants (such as Triton X-100) for assaying analytes in samples containing hemoglobin, and Oshiro *et al.* taught the use of the surfactants SLS and Triton X-100 in methods of hemoglobin determination.

The Oshiro *et al.* reference was only brought in for its teachings of SLS, not for its use in conjunction with an alkaline substance, which would make further enzyme analysis difficult as the pH would be significantly raised. Therefore, the reference does not teach away from the use of a functionally equivalent surfactant as alleged by the Applicant. In response to applicant's argument that the two references are nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, both references are drawn to the use of surfactants in the determination of either hemoglobin itself, or in conjunction with other compounds to remove the influence of hemoglobin. In either case, the surfactant functions in exactly the same manner.

Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

7/17/07

/Patricia Leith/
Patricia Leith
Primary Examiner
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